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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,406	02/09/2004	David J. Burke	034008-003	6608

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
04/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/773,406	BURKE ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *02 March 2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-5,7-12,15-17,23,29-32,41 and 43-45*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Michael Szperka/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because:
Claims 1-5, 7-12, 15-17, 23, 29-32, 41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6, 914,128 B1, of record, in view of Gordon et al. (Gastroenterology, 2001, 121:268-274, of record) for the reasons set forth in the office action mailed 9/2/08.

Applicants' arguments filed on 3/2/09 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the conditions and data disclosed by the'128 patent cannot be extrapolated to another monoclonal antibody because of the specificity and efficacy of the monoclonal antibody. Therefore, an ordinary skilled in art would not have an expectation of success with the formulation of the '128 patent.

Applicants further traversed the rejection based on that the substitution of an antibody formulation with other buffer because of antibodies differ with its specificity and highly relevant to their behavior and efficacy in a formulation. Applicants further argued that the claimed antibody is IgG4 while the referenced antibody is IgG1.

However, as taught in the '128 patent, the referenced stabilizing formulation is suitable to enhance the shelf life or effectiveness of the antibody formulation for various molecular targets which are structurally unrelated (col. 72-76, in particular) including cell surface molecules designated CD's, cytokines, growth factors, receptors and its ligands as well as enzyme inhibitors. The '128 patent also allows the combination of target molecules (col. 77-78, in particular). Moreover, the '128 patent teaches that the expression of antibody (col. 68, lines 29-45) encompasses both IgG1 and IgG4 and the formulation disclosed is suitable to stabilize IgG4 as well.

Unlike Applicants assertion that the '128 patent disclose a broad range of ingredients, the '128 patent discloses 4 choices of buffers that are well known in the antibody formulation art, histidine, sodium succinate, citrate and phosphate.

As intergrins are cell surface molecules, and the referenced formulation is suitable for antibodies to other cell surface molecules, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the antibody in the formulation taught by the '128 patent with the natalizumab antibody as taught by Gordon et al. Therefore, one of the ordinary skill in the art would have had a reasonable expectation of success. It is reminded that the obviousness rejection does not require absolute predictability but only the reasonable expectation of success. MPEP 2143.02.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody formulation taught by the '128 patent can be used for enhancing shelf life and effectiveness of antibody formulation. As the formulation stabilizes any antibody, it is expected that the antibody formulation taught by the '128 patent would stabilize the natalizumab taught by Gordon et al. as well.

From the teachings of the references, it would be obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the combination of the references remains obvious.

Yunsoo Kim
Patent Examiner
Technology Center 1600
April 21, 2009

/Michael Szperka/
Primary Examiner, Art Unit 1644